

K230754 L12 LED Light Source with AIMApr 11, 2023
25 days to decisionK230754 · Product code: **OWN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k230754/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Confocal Optical Imaging (OWN)
Date received	Mar 17, 2023
Decision date	Apr 11, 2023
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker
Location	Portage, MI, US
Contact	April Malmborg
Website	http://www.stryker.com/
510(k) history	92 submissions · 92 cleared · 2006-2023

Stryker is a family of eight-wheeled armored fighting vehicles derived from the Canadian LAV III. The vehicles are produced by General Dynamics Land Systems-Canada for the United States Army in London, Ontario. This historical record documents FDA 510(k) cleared devices from total submissions between 2006 and 2023. The company's regulatory portfolio focused primarily on General & Plastic Surgery devices, including advanced imaging systems, LED light sources, and surgical visualization equipment. The company has been inactive, with no clearances recorded in more than five ...